June 23, 2010
(https://www.genengnews.com/wp-content/uploads/2018/08/June23_2010_22415259_ColorfulEyeball_FDAapprovesGenentechsLucentis_Ed

Drug is already sanctioned for wet AMD and brought in over $1 billion in sales last year.

FDA has approved Lucentis® for the treatment of macular edema following retinal vein occlusion (RVO) after a six-month priority review. "In the Lucentis RVO clinical trials significantly more people treated with monthly Lucentis showed sustained vision improvement during the six-month study with an effect seen as early as seven days," points out Hal Barron, M.D., evp, global development and CMO.

Lucentis was discovered by Genentech, a member of the Roche group, and is being developed by Genentech and Novartis for diseases or disorders of the eye. The drug was sanctioned for the treatment of wet age-related macular degeneration (AMD) in 2006.

Genentech retains commercial rights in the U.S., and Novartis has exclusive commercial rights for the rest of the world. Lucentis drew in almost CHF 1.2 billion (about $1.08 billion) in U.S. sales last year, a 24% increase from 2008, according to Roche.

Lucentis is a vascular endothelial growth factor (VEGF) inhibitor. In RVO, angiogenesis and hyperpermeability can lead to macular edema, the swelling and thickening of the macula.

Sanction in RVO was based on the outcome of the BRAVO and CRUISE studies. The BRAVO study was conducted in 397 patients with macular edema following branch-RVO. The CRUISE study enrolled 392 patients with macular edema following central-RVO. During the first six-month period, participants in both trials received monthly injections of either 0.3 mg or 0.5 mg of Lucentis or monthly placebo injections. The primary endpoint of both studies was mean change from baseline in best-corrected visual acuity at six months.

Patients in BRAVO who received 0.5 mg of Lucentis had a mean gain of 18.3 letters compared to 7.3 letters in patients receiving sham injections, according to Genenetech. In the CRUISE study patients who received 0.5 mg of Lucentis had a mean gain of 14.9 letters compared to 0.8 letters for those getting placebo, the firm adds.

In BRAVO and CRUISE, the most common ocular adverse events that occurred in the Lucentis arms included conjunctival hemorrhage (48%) and eye pain (17%). Among nonocular serious adverse events in the BRAVO study, two events occurred in the Lucentis 0.5 mg dose group: one cerebrovascular accident that resulted in death and one myocardial infarction. In CRUISE, nonocular serious adverse events were uncommon and included one case of either myocardial infarction or acute coronary syndrome in each of the three groups.

Lucentis has previously been associated with detached retina and serious eye infection. Increases in eye pressure have been seen within one hour of an injection. Although uncommon, conditions associated with eye- and noneye-related blood clots may occur. Serious side effects include inflammation inside the eye and, rarely, effects related to the injection procedure, such as cataract, according to Genentech.